

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IN 03/00323

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/48 A61K31/4439

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ①	WO 01/24780 A (VENKATESWARA RAO PAVULURI ; KHADGAPATHI PODILI (IN); NATCO PHARMA LTD) 12 April 2001 (2001-04-12) cited in the application the whole document	1-26
X ②	WO 94/27988 A (ASTRA AB ; LINDBERG PER LENNART (SE); VON UNGE SVERKER (SE)) 8 December 1994 (1994-12-08) the whole document	1-26
Y ③	WO 01/14367 A (WHITTALL LINDA ; APPLIED ANALYTICAL IND INC (US); JENKINS DOUGLAS JOHN) 1 March 2001 (2001-03-01) the whole document	1-26
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

4 June 2004

Date of mailing of the international search report

14/06/2004

Name and mailing address of the ISA

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y (u)	EP 0 960 620 A (RANBAXY LAB LTD) 1 December 1999 (1999-12-01) the whole document	1-26
Y (2)	DATABASE CHEMABS CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; LEE, S-J ET AL.: "Omeprazole enteric-coated soft capsules" XP002164221 Database accession no. 133:242640 abstract	1-26
Y (6)	DE 32 22 476 A (WARNER LAMBERT CO) 15 December 1983 (1983-12-15) cited in the application the whole document	1-26
A (2)	WO 98/50019 A (CHEN JIVN REN ; SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12) the whole document	1-26
A (8)	US 4 138 013 A (OKAJIMA YAKUTARO) 6 February 1979 (1979-02-06) the whole document	1-26
A (A)	US 5 877 192 A (LINDBERG PER ET AL) 2 March 1999 (1999-03-02) cited in the application the whole document	1-26
A (2)	WO 02/39980 A (LEK TOVARNA FARMACEVTSKIH ; SIRCA JUDITA (SI)) 23 May 2002 (2002-05-23) the whole document	1-26

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## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1,14 partially  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1,14 partially

Present independent claims 1 and 14 lack clarity within the meaning of Article 6 PCT. First, the claims taken as a whole are inconsistent between each other: it remains unclear whether the enteric polymer is "mixed into gelatin" for forming the shell (claim 1) or whether the enteric polymer is "coating the gelatin shell" (claims 3 and 16). Second, claims 1 and 14 are unclear because rabeprazole is not an enantiomer of omeprazole. It remains unclear whether claims 1 and 14 are directed to formulations containing pure enantiomeric forms of omeprazole, mixtures of pure enantiomeric forms of omeprazole, or other compounds analogous to omeprazole (benzimidazole derivatives). The lack of clarity arises to such an extent as to render a meaningful search of the claims impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear, namely formulations wherein i) the shell material comprises a mixture of gelatin and enteric polymer; and ii) the active comprises omeprazole or its S-form (esomeprazole).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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